

was added; in Fig. 38, "64" was deleted and "134" was replaced with "54"; in Fig. 45, "878" was added; and in Figs. 47, 48, 51 and 52, "607" was deleted for consistency with the description. In Fig. 70, "804" was replaced with "800" to eliminate the double occurrence of "804." In Fig. 73, "72" was replaced with "506" for consistency with Fig. 72.

Entry and consideration of this Amendment prior to the examination of the above-identified application is respectfully requested.

If there are any fees due in connection with the filing of this Amendment, please charge our Deposit Account Number 50-1066. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the papers accompanying this response, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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PATENT
Attorney Docket No. 101.0056-03000
Customer No. 22882
Express Mail Label No. ET747368548US

CHANGES TO THE TITLE

Please amend the title as follows:

SINGLE-LOCK ANTERIOR CERVICAL PLATING SYSTEM,
~~INSTRUMENTATION, AND METHOD OF INSTALLATION~~

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PATENT
Attorney Docket No. 101.0056-03000
Customer No. 22882
Express Mail Label No. ET747368548US

CHANGES TO THE SPECIFICATION

Please amend the specification as follows:

Page 2, paragraph 1:

This is a divisional of application Serial No. 09/022,293, filed February 11, 1998, and claims the benefit of U.S. provisional application no. 60/037,139 filed February 11, 1997, incorporated herein by reference. ~~This application claims priority of Application Serial No. 60/037,139 filed February 11, 1997, incorporated herein by reference.~~ Application Serial No. 08/____, ____ (Attorney Docket No. ~~P-13408~~) 09/022,344 filed February 11, 1998, and titled SKELETAL PLATING SYSTEM, now U.S. Patent No. 6,139,550, is incorporated herein by reference.

Paragraph bridging pages 38 and 39:

Referring to FIG. 22, another alternative embodiment of a multiple locking plate is shown and is generally referred to by the number 230. The plate 230 uses threaded caps, such as cap 300 shown in FIGS. 9 and 23, for a locking element or preferably one with cut outs as described having an appearance in a top view such as the locking element in FIGS. 10-11, for example. The central locking hole ~~602-232~~ has an elongated slot 234 for providing an increased compression capability, as will be discussed further herein.

Paragraph bridging pages 39 and 40:

Referring to FIGS. 6 and 10-13, it will be appreciated that when the locking elements 20, 21 are rotated in the clockwise direction with respect to the

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view of FIG. 6, a respective bearing surface 48 (as best seen in FIG. 21) will ride upon the curved top surface 39 of a respective bone screw head 32 in order to positively lock the associated bone screws 30 and the locking elements 20, 21 in place.

Page 40, first full paragraph:

Alternatively, as shown in ~~FIG. 21~~ FIGS. 12 and 13 in place of a bearing surface-4448, a ramp or wedge shaped surface 44 may be used to increase the force applied to the bone screw head 32. When locked, the leading end of the ramped portion of the locking element would be lower than the prominence of the bone screw head 32 so that more force is needed to lift the locking element and untighten it than is needed for the locking element to remain tight and locked. However, the locking element heads 23 need not have slots, be cammed, or have a ramped surface to achieve the locking of the bone screw 30 in place. Pressure, friction, interference fits, or other engagement means capable of preventing the locking element from moving from its locked position may be employed.

Paragraph bridging pages 40 and 41:

The rivet 202, shown in FIGS. 17-20 is intended for use in association with plate 70 shown in FIGS. 14-15, is shown in detail in cross section in FIGS. 19 and 20. The rivet 202 has a head 204, a shaft 206, and an elongated bottom segment 208 for fitting within the corresponding opening 200 in the plate 70. The lower surface 210 of the head 204 of the rivet 202 has an irregular surface which may be cammed, such as on the bottom of locking element 20, 21, for engaging

the top surface 39 of the bone screw head 32. For use in the end locking holes 19, the upper surface of the elongated bottom segment 208 can have an irregular surface for cooperating with the irregular surface of the bottom of the plate 70 to hold the rivet 202 in the locked position against the bone screw head 32, as shown in FIG. 15. While the rivet of FIG. 18 is a separate, removable component from the plate, the rivets, and particularly those for use with the end locking holes, can be formed as part of the plate during the manufacturing process of the plate and rivet can be ~~non~~non-removable.

Page 54, second full paragraph:

In FIG. 46 an alternative embodiment of the plate holder 890 is shown. A single solid member 890 has a threaded projection 894 at its bottom end for attachment to the central threaded locking hole 12 in the plate. The bottom surface of the holder 890 of this embodiment is contoured so as to match the contours of the top surface of the plate adjacent to the locking hole 12, shown as a depression 14 (FIG. 1).

Paragraph bridging pages 55 and 56:

FIG. 69A is an alternative embodiment of the plate holder 850. A single solid member 852 has a threaded projection 854 at its bottom end for attachment to the central threaded locking hole 12 in the plate. The solid member 852 could also be threaded into a bone screw receiving hole 6. The bottom surface of the holder 850 of this embodiment is contoured so as to match the contours of the top surface of the plate adjacent to the locking hole 12, shown as a depression 14 (FIG. 1).

Page 56, second full paragraph:

Referring to FIG. 70, an alternative embodiment of the plate holder referred to by the number 800' is shown in which there is a removable handle 860 that is used for first attaching the plate holder 800' to the plate, by rotating the shaft 804, and then for holding the plate holder 800' off to the side by extension 864, during the attachment procedure reducing the interference of the plate holder ~~800~~800' with the surgical procedure.

Page 57, first full paragraph:

Referring to FIGS. 38-39, compression tool 100 includes a second moveable compression arm 130 movable along toothed bar 102 parallel to first compression arm 104. The distal end of the second compression arm 130 also has a bore 132, the same as bore 106, that can receive a removable ~~post~~134compression post 54. Bores 106 and 132 are the same so that either compression arm 104, 130 can be used to hold the removable ~~post 134~~compression post 54, permitting the compression tool 100 to be used in any orientation. By permitting the plate engaging element 108 and the compression post 54 to both rotate and slide in the bores 106, 132 of the two compression arms 104, 130, with the plate engaging hook 110 able to work even at an angle to the plate allows for the apparatus to be readily attachable to the spine through the compression post 54 and plate.

Page 58, first full paragraph:

Compression arm 130 has a driving assembly consisting of a toothed wheel (not visible) which is engaged with the tooth gear 138 of bar toothed gear

102 and is connected to compression arm 130 such that compression arm 130 is movable along the length of toothed gear bar 102 by means of the rotation of handle 140, which is connected to the toothed wheel. When the handle 140 is turned in the direction of the arrow shown in FIG. 38, compression arm 130 is moved toward compression arm 104. The driving assembly has a self lock release mechanism whereby the movement of the two compression arms 104, 130 away from one another is prevented, without the activation of the release. On the inward distal end of each compression arm, on facing sides, is a notch 142 or recess for holding the plate 2 along its sides between the central lobes 4 and end lobes 4, as shown in FIG. ~~37~~ 38.

Paragraph bridging pages 60 and 61:

As shown in FIGS. 31 and 32, pilot hole forming apparatus 60 includes a hollow cylindrical housing 62 having a bottom provided with a through hole 63. Housing 62 contains a central shaft 64 which extends through the through hole 63 in the bottom of housing 62. The leading end 66 of shaft 64 tapers gradually to a sharp point 65. Shaft 64 is provided with a ring member ~~73~~ 78 having a diameter which closely corresponds to the inner diameter of housing 62 to guide the travel of shaft 64 within housing 62. A compression spring 67 is interposed between the ring member ~~73~~ 78 and the bottom of housing 62. Compression spring 67 provides a bias force which normally urges the sharp point 65 into a retracted position within housing 62. The upper end of shaft 64 has an enlarged head 68 extending outside of the housing 62 which is intended to be manually depressed or struck by a percussion instrument in order to drive the sharp point

65 out of housing 62 and into a vertebral body 50a. Shaft 64 is given a length, taking into account the length that spring 67 will have when fully compressed, to determine the maximum depth of the pilot hole formed in a vertebral body. The depth is selected to assure that the pilot hole does not reach the posterior cortex of the vertebral body, which borders the spinal canal.

Page 65, first full paragraph:

Since the plate is attached to vertebrae 50a by means of bone screws 30 and compression post ~~64~~54 is fixed to the adjacent vertebrae 50b, movement of the first and second compression arms 104 and 130 in the direction of vertebrae 50a by rotation of handle 140 results in compression of the bone graft construct 51 between the adjacent vertebrae 50a and 50b. The distance of several millimeters is sufficient for compression of the bone graft construct 51. Once the desired compression is obtained, bone screw pilot holes can be formed in vertebral body 50b by means of pilot hole forming apparatus 60, as described above, for insertion of bone screws 30 into bone screw receiving holes 8 of bone plate 2, fixing the plate 2 to the adjacent vertebrae 50b. Compression tool 100 can then be withdrawn by activation of the release.

Page 67, first full paragraph:

It is recognized that other variations in the order of compression may be employed. For example, during the compression of the fusion graft construct 51 between vertebrae 50b and 50c, the hook 110 of ~~compression tool 100~~plate engagement element 108 may engage the notch 18 in the end of the plate 2, and the other compression arm of the compression tool 100 may engage the

compression post 54 in the third adjacent vertebrae 50c. It should also be noted that plate 2 has a recess end cut out portion between the lobes at the end of the plate for insertion of the compression post 54 in the vertebrae. Otherwise, there may not be room below the end of the plate 2 for insertion of the compression post 54.

Paragraph bridging pages 68 and 69:

FIG. 43 is a cross-sectional view in the plane of the center of the two end locking screw holes 6 of plate 2, with two bone screws 30 in their installed positions and locking element 21 in its locking position. FIG. 44 is an enlarged view of one of the bone screws 30 in plate 2 of FIG. 43. In a preferred embodiment, the axis of each screw 30 is generally perpendicular to tangents to the upper and lower surfaces of plate 2 at points which are intersected by the longitudinal axis of the associated bone screw 30. Thus, because of the curvature of plate 2 in the plane of FIG. 43, bone screws 30 can be directed so as to converge toward one another at a desired angle. Preferably, such angle will be greater than 14°. More preferably, such angle will be greater than 14° and less than 30°. The axis of the two bone screws 30 shown in FIG. 43 may subtend an angle of about 45°. Alternatively, the curvature of the plate from side to side may be so as to conform to the surface of the anterior aspect of the human adult cervical spine and the axis of the paired screw hole may deviate from being perpendicular to the plate when viewed on end to achieve optimal convergence.

Page 69, second full paragraph:

A plating system according to each of the above embodiments can be installed in the same manner as described above, and using the same instruments and tools, as illustrated and described above with respect to the first embodiment. In the case of the embodiment shown in FIG. 22, the compression operations would be performed by means of slot ~~604~~ 232 instead of the middle locking screw hole 12.

Page 71, first full paragraph:

FIG. ~~63~~ 65 shows two bone screws 170 and associated threaded locking caps 610 in their fully installed positions. In these positions, head portions 174 and 176 of each bone screw 170 form an interference fit with corresponding portions of an associated bone screw receiving hole 602. Rim 612 of each threaded locking cap 610 forms an interference fit with upper portion 178 of the head of its associated bone screw 170. Because the thread 608 of each locking cap 610 mates precisely with the internal thread in an associated bone screw receiving hole 602, each threaded locking cap 610 is additionally subjected to a clamping force between associated head portion 178 and the internal threads 603 of associated bone screw receiving hole 602. The rounded head 614 of each threaded locking cap 610 assures that the upper surface of an assembled plating system will be free of sharp edges, or projections.

Paragraph bridging pages 72 and 73:

As shown in Figure 80, the operation of the bone screw and locking element driver 1000 is as follows: the cap 610 is inserted onto the end of the cap driver 1004, and then the cap driver 1004 with the shaft 1010 of the bone screw

driver passing through the central longitudinal opening of the cap driver. As shown, the bone screw driver shaft 1010 passes through the recess 306 in the cap 610 and engages the recess 180 in the head of the bone screw 170. The bone screw 170 is shown being installed in a bone screw receiving hole in the plate 600. The handle (not shown) of the bone screw driver is rotated, thereby screwing the bone screw 170 in place. Since the diameter of the bone screw driver is less than the width of the recess 306 of the cap 610, the bone screw driver shaft 1010 is able to rotate without rotation of the cap 610.

Paragraph bridging pages 73 and 74:

In FIG. 81, an alternative embodiment of the combination bone screw and locking cap driver is shown. In this embodiment, a housing is not used. Instead, the cap-driver shaft 1010 holds the cap 610 by friction and the handle 620 for the bone screw driver shaft 1010 is rotated. A ball spring ~~622~~-assembly 622 holds the cap driver 1002 up until the bone screw has been screwed into the bone screw receiving hole. Driver 1010 has an elongated portion that once the bone screw has been installed, the ball spring 622 is depressed and the handle 624 associated with the cap driver is permitted to descend for rotation of the cap 610. A tubular housing can be employed to assist in aligning of the cap 610 in the bone screw receiving hole, as indicated above.

Page 74, last paragraph:

FIGS. ~~54-56~~ 53-55 show a bone screw 170 for use with the single locking plating system according to the invention. Bone screw 170 differs from bone screw 30 previously described in detail, only with regard to the stepped

configuration of head 172. Preferably, bone screw 170 includes a lower portion 174 which is contiguous with the screw shank and has a reduced diameter equal to the maximum diameter of the shank 176. Portion 178 of head 172 also has smaller diameter than lower portion 174. The thread 182 has the same configuration as for the bone screw 30 discussed above. However, either embodiment of bone screws can be used with any of the plates.

Page 77, first full paragraph:

While the plate instrumentation and method have been described in association with attaching a plate to the vertebrae of the spine, it should be appreciated that the plates can be adopted for specification to other partsies of the body. See, for example, Application Serial No. 09/022,344, filed February 11, 1998, and titled Skeletal Plating System, now U.S. Patent No. 6,139,550, incorporated by reference above. However, the dimensions of the plate, the specific contours and placement of the bone screw receiving holes would have to be modified.